Parts F, G, H

21 CFR Part 111 Proposed Regulation Changes
(Blue Text Indicates ALI Suggested Modifications)

SUBPART F HOLDING AND DISTRIBUTING

111.80 WHAT PRODUCTION REQUIREMENTS APPLY TO HOLDING COMPONENTS, DIETARY INGREDIENTS, DIETARY SUPPLEMENTS, PACKAGING, AND LABELS?
No Recommended Changes for this section.

111.82 WHAT REQUIREMENTS APPLY TO HOLDING IN-PROCESS MATERIALS?
No Recommended Changes for this section.

111.83 WHAT REQUIREMENTS APPLY TO HOLDING RESERVE SAMPLES OF COMPONENTS, DIETARY INGREDIENTS, AND DIETARY SUPPLEMENTS?
No Recommended Changes for this section.

111.85 WHAT REQUIREMENTS APPLY TO RETURNED DIETARY INGREDIENTS OR DIETARY SUPPLEMENTS?
No Recommended Changes for this section.

111.90 WHAT REQUIREMENTS APPLY TO DISTRIBUTING DIETARY INGREDIENTS OR DIETARY SUPPLEMENTS?
No Recommended Changes for this section.

SUBPART G CONSUMER COMPLAINTS

111.95 WHAT REQUIREMENTS APPLY TO CONSUMER COMPLAINTS?
No Recommended Changes for this section.

SUBPART H RECORDS AND RECORD KEEPING

111.125 WHAT REQUIREMENTS APPLY TO RECORDKEEPING?

Recommended Changes: Paragraph (a): You must keep written records required by this part for one (1) year beyond the product life on the product label or two (2) years from the date of manufacture pertaining to that specific batch or lot of dietary ingredients or dietary supplements.

Recommended Changes: Paragraph (c): You must have all records required under this part, or copies of such records, readily available during the retention period for authorized inspection ~~and copying by FDA when requested.~~ This sentence, without strikeouts, violates manufacturer rights to privacy of corporate and trade secrets of unique and critical manpower, material sources, production processes, product testing, and product distribution.